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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	No. MDL 15-02641-PHX-DGC
Lisa Hyde and Mark E. Hyde, a married couple, Plaintiffs, v. C. R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation, Defendants.	No. CV-16-00893-PHX-DGC **ORDER**

The case brought by Plaintiffs Lisa and Mark Hyde is set for a bellwether jury trial on September 18, 2018. During the final pretrial conference held on September 6, 2018, it became clear that the parties disagree on whether Plaintiffs' negligence per se claim is impliedly preempted under 21 U.S.C. § 337(a). The issue was raised and briefed by the parties in their proposed final pretrial order and jury instructions. Docs. 12388 at 8-12, 12438 at 54-61. The Court asked the parties during the pretrial conference whether they required further briefing and whether they wished to have this issue resolved before trial. Counsel for both sides stated that no further briefing was needed and that a ruling before trial would be helpful.

For the reasons stated below, the Court finds that the negligence per se claim is preempted. This conclusion is purely legal – it is not affected by the evidence that would be presented at trial. As a result, the Court concludes that it should enter judgment on this claim before trial under Rule 56 of the Federal Rules of Civil Procedure. Although decisions under that rule normally are made in response to a formal motion for summary judgment, the rule makes clear that the Court may enter summary judgment *sua sponte*, provided the parties are notified of the Court's intention to make a dispositive decision and have an opportunity to respond. *See* Fed. R. Civ. P. 56(f); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 326 (1986) ("district courts are widely acknowledged to possess the power to enter summary judgments *sua sponte*, so long as the losing party was on notice that she had to come forward with all of her evidence"). In this instance, the question is purely one of law, the parties have been fully heard, and the parties seek a decision before trial. Such a decision will enable the parties to allocate their time and evidence to the issues to be considered by the jury.[1]

I. Background.

Plaintiff Lisa Hyde received a Bard IVC filter implant in 2011. In 2014, she learned that the filter had tilted, perforated the IVC wall, and fractured. The filter and fractured limbs were removed three months later.

Mrs. Hyde and her husband assert various claims. Doc. 364; Doc. 1, Case No. CV-16-00893. Applying Wisconsin law, the Court granted summary judgment to Defendants on several claims. Doc. 12007. Plaintiffs continue to assert claims for strict liability design defect (Count III), negligent design (Count IV), negligence per se (Count IX), loss of consortium (Count XV), and punitive damages. *Id.* at 19.[2]

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[1] Another approach would be to treat this issue as a motion by Defendants for judgment as a matter of law under Rule 50. Although the standard for deciding such a motion is the same as the standard under Rule 56, the Ninth Circuit has held that a Rule 50 motion cannot be made before trial. *See McSherry v. City of Long Beach*, 423 F.3d 1015, 1019-22 (9th Cir. 2005). The Court accordingly will enter judgment under Rule 56.

[2] Defendants have explained that they did not seek summary judgment on the negligence per se claim because they did not know the basis for the claim until the parties

II. Discussion.

Under Wisconsin law, negligence per se is a form of negligence that results from violation of a statute. *See Friederichs v. Huebner*, 329 N.W.2d 890, 917 (Wis. 1983). For the violation of a safety statute to constitute negligence per se, the plaintiff "must show: (1) the harm inflicted was the type the statute was designed to prevent; (2) the person injured was within the class of persons sought to be protected; and (3) there is some expression of legislative intent that the statute become a basis for the imposition of civil liability." *Tatur v. Solsrud*, 498 N.W.2d 232, 235 (D. Wis. 1993) (citing *Walker v. Bignell*, 301 N.W.2d 447, 454 (Wis. 1981)).

Plaintiffs do not allege violation of a Wisconsin statute as part of their negligence per se claim. Rather, they contend that Defendants violated various provisions of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and related federal regulations, in designing the Bard filter. Docs. 12388 at 8-9 (final pretrial order), 12400 at 4-7 (trial brief), 12438 at 54-59 (proposed jury instructions). Specifically, Plaintiffs allege violations of 21 U.S.C. §§ 321, 331, and 352, and 21 C.F.R. §§ 803, 806.1, 820.100, 820.198, and 820.250. *Id.*; *see* Doc. 364 ¶ 231.

As noted above, the third element of Wisconsin's negligence per se claim requires "some expression of legislative intent that the statute become a basis for the imposition of civil liability." *Tatur*, 498 N.W.2d at 235. As other courts have recognized, however, "[f]ar from containing an expression that FDA regulations are intended to form the basis for civil liability, the [FDCA] expresses the opposite intention." *Cali v. Danek Med., Inc.*, 24 F. Supp. 2d 941, 954 (W.D. Wis. 1998). Under § 337(a), "[v]iolations of the FDA are enforceable only by the United States." *Id.* "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Thus, "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a

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prepared the proposed final pretrial order.

claim for violating the FDCA – that is, when the state claim would not exist if the FDCA did not exist." *Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *7 (N.D. Ga. Aug. 19, 2011) (citation omitted); *see Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002) (noting that under § 337(a) "no private right of action exists for a violation of the FDCA").

In *Buckman*, the Supreme Court held that a state law claim that a defendant made fraudulent statements to the FDA, in violation of the FDCA, was impliedly preempted by § 337(a) because the claim "exist[ed] solely by virtue" of FDCA requirements and therefore "would not be relying on traditional state tort law which had predated the [FDCA]." 531 U.S. at 353. The same is true here. Plaintiffs' "claim of negligence per se would not exist prior to the enactment of the FDCA . . . because the claim only alleges violation of that law." *Leonard*, 2011 WL 3652311, at *8. As in *Buckman*, Plaintiffs' "negligence per se claim (or, more appropriately characterized, [their] negligence claim based solely on violations of . . . FDA regulations) is impliedly preempted by the FDCA." *Grant v. Corin Grp. PLC*, No. 3:15-CV-169-CAB-BLM, 2016 WL 4447523, at *4 (S.D. Cal. Jan. 15, 2016); *see Connelly v. St. Jude Med., Inc.*, No. 5:17-cv-02005-EJD, 2017 WL 3619612, at *5 (N.D. Cal. Aug. 23, 2017) (negligence per se claim preempted where it was "based entirely on violations of the FDCA and its implementing regulations"); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 862 (W.D. Tenn. 2015) ("If Plaintiffs claim negligence based solely on Defendants' failure to comply with federal law or solely on illegal off-label promotion (i.e. negligence per se), Plaintiffs' claims are impliedly preempted under *Buckman*."); *Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK AJWX, 2014 WL 3056026, at *6 (C.D. Cal. June 25, 2014) ("[A] negligence per se claim alleging violation of the FDCA is nothing more than a private right of action under the FDCA for damages. Since the latter is not available as a result of § 337(a), the Court finds that the former is preempted as well."); *McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1200 (M.D. Fla. 2013) ("Plaintiff's attempt to recast a claim for violation of the FDCA as a state-law negligence claim is impliedly barred by § 337(a)."); *Franklin v.*

Medtronic, Inc., No. 09-cv-02301-REB-KMT, 2010 WL 2543579, at *8 (D. Colo. May 12, 2010) ("[T]o the extent that Plaintiff seeks to ground her negligence per se . . . claim[] on allegations that Defendant violated the FDCA – namely, by selling a misbranded and adulterated product – these claims are impliedly preempted pursuant to 21 U.S.C. § 337(a)."); *Talley v. Danek Med., Inc.*, 7 F. Supp. 2d 725, 731 (E.D. Va. 1998) ("[T]he FDCA expressly prohibits the bringing of a private cause of action under the Act. To allow a state negligence per se action based upon alleged violations of the FDCA would defeat the purpose of that prohibition.").

Plaintiffs' citation of *Garross v. Medtronic, Inc.*, 77 F. Supp. 3d 809, 816 (E.D. Wis. 2015), is not persuasive. Doc. 12388 at 9-10. The plaintiff in that case did not bring a negligence per se claim, but instead asserted traditional common law torts such as design defect, failure to warn, and negligence. *Garross*, 77 F. Supp. 3d at 813. Those claims were not impliedly preempted under *Buckman* "because none of them [arose] solely from a violation of federal law; rather, each [arose] from an independent, well-recognized duty owed under state law." *Id.* at 816; *see also Hoffmann v. Wis. Elec. Power Co.*, 664 N.W.2d 55, 62 (Wis. 2003) (noting that "the enactment of safety statutes . . . does not abolish the duty arising under common-law negligence"). In this case, Plaintiffs retain and will assert at trial a common law negligent design claim; that claim is not affected by this ruling.

Plaintiffs cite cases holding that violations of FDCA regulations may support negligence per se claims in Wisconsin. Doc. 12388 at 9-10 (citing *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 964 (E.D. Wis. 1981) (pre-*Buckman* decision holding that violation of federal regulation for prescription drug labeling supported negligence per se claim under Wisconsin law); *Marvin v. Zydus Pharms. (USA) Inc.*, 203 F. Supp. 3d 985, 992 (W.D. Wis. 2016) (finding that plaintiffs may bring a negligence per se claim under Wisconsin law based on a violation of federal medication guide regulations); Doc. 12400 at 13 (citing *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 874 (Wis. Ct. App. 2004) ("In Wisconsin, violations of the FDA regulations may constitute negligence

per se.")). But these cases are squarely at odds with § 337(a). The plain language of that section and the *Buckman* decision indicate that such claims fail. *See Dunbar*, 2014 WL 3056026, at *6. Even if state law recognizes the claims, federal law preempts them. *See Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (finding state law claim preempted where the plaintiff was not suing under state law for conduct that happens to violate the FDCA, but instead is suing solely "*because* the conduct violates the FDCA.") (emphasis in original). This Court reached the same conclusion in previous bellwether cases. *See* Docs. 8874 at 14-18, 10404 at 14-17 (finding negligence per se claims impliedly preempted in the Booker and Jones bellwether cases).

IT IS ORDERED that judgment is entered in favor of Defendants on Plaintiffs' negligence per se claim (Count IX).

Dated this 11th day of September, 2018.

David G. Campbell
Senior United States District Judge